

**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

ENZO LIFE SCIENCES, INC.,)	
)	
Plaintiff,)	
)	
v.)	
)	C.A. No. 12-106-LPS
ROCHE MOLECULAR SYSTEMS, INC.,)	
ROCHE DIAGNOSTICS CORPORATION;)	
ROCHE DIAGNOSTICS OPERATIONS,)	
INC.; and ROCHE NIMBLEGEN, INC.,)	
)	
Defendants.)	

**MOTION FOR LEAVE TO FILE
FIRST AMENDED ANSWER TO AMENDED COMPLAINT**

Pursuant to Federal Rule of Civil Procedure 15, Defendants Roche Molecular Systems, Inc., Roche Diagnostics Corporation, Roche Diagnostics Operations, Inc., and Roche Nimblegen, Inc. (collectively, “Roche”), hereby move this Court for an order granting it leave to file the First Amended Answer to Amended Complaint and Counterclaims (“Amended Answer”), attached hereto as Exhibit A. The Amended Answer includes a counterclaim for patent misuse and an affirmative defense and a declaratory judgment counterclaim that U.S. Patent No. 7,064,197 (the ’197 patent) is unenforceable by reason of inequitable conduct. The Amended Answer also includes several other additions and deletions from the previously filed answer as evidenced in the attached redline, attached hereto as Exhibit B pursuant to D. Del. LR 15.1. Defendants make this motion to amend in good faith, not for any dilatory purpose, and prior to the deadline for amendments to pleadings ordered by this Court in its Scheduling Order. (D.I. 48).

Roche requests that the Court grant it leave so that it may assert a claim and affirmative defense of inequitable conduct with respect to the ’197 patent, as well as a claim of patent

misuse. When Roche filed its Answer to Amended Complaint and Counterclaims (D.I. 21), Roche did not have the proper factual basis to assert these claims and defenses. *See, e.g., Garr v. U.S. Healthcare, Inc.*, 22 F.3d 1274, 1278 (3d Cir. 1994) (“The signer’s signature on a pleading. . . certifies the signer has . . . made a reasonable inquiry into the contents of the pleading. . . and concluded that it is well grounded in fact and warranted in law. . .”). Since filing its original Answer to Amended Complaint and Counterclaims, Roche has become aware of facts that substantiate the pleading of these claims and defenses.

I. ARGUMENT

A. Legal Standards

The Supreme Court has held that “leave to amend ‘shall be freely given when justice so requires.’” *Foman v. Davis*, 371 U.S. 178, 182 (1962) (quoting Fed. R. Civ. P. 15(a)). Additionally, “[t]he Third Circuit has adopted a liberal approach to the amendment of pleadings.” *Micron Tech., Inc. v. Rambus Inc.*, C.A. No. 00-792-JJF (D.I. 979) (D. Del. July 12, 2007) (citing *Dole v. Arco Chem. Co.*, 921 F.2d 484, 486-87 (3d Cir. 1990)). “Where the non-moving party will not suffer substantial or undue prejudice, denial of leave to amend must be based on bad faith or dilatory motives, truly undue or unexplained delay, repeated failures to cure the deficiency by amendments previously allowed, or futility of amendment.” *Accenture Global Servs. GMBH v. Guidewire Software Inc.*, 631 F. Supp. 2d 504, 509 (D. Del. 2009) (Robinson, J.) (quoting *USX Corp. v. Barnhart*, 395 F.3d 161, 166 (3d Cir. 2004)) (internal quotation marks omitted). None of those circumstances exist in this case.

B. ROCHE’s Motion Satisfies the Liberal Standard for Amendment

Roche’s motion for leave to amend meets the liberal standard for amendment. First, Enzo Life Sciences, Inc. (“Enzo”) will not suffer prejudice as a result of Roche’s amendment.

The parties remain in the midst of fact discovery, to be completed by June 17, 2014, no depositions have yet been noticed or taken, and no trial date has been set. Enzo has known of the facts surrounding Roche's defenses and counterclaims, and specifically, the alleged misrepresentations of the inventors of the '197 patent. Moreover, Enzo has had, and continues to have, every opportunity to gain the relevant discovery necessary from the inventors and other relevant persons. Second, Roche does not move in bad faith or for dilatory tactics. Roche has diligently investigated potential inequitable conduct and patent misuse claims and defenses, and in good faith alleges facts to support those claims and defenses. Third, Roche timely moves to amend its answer within the deadline for the amendment of pleadings set for January 15, 2014. Finally, Roche has sufficiently pled its inequitable conduct claims and defenses under Rule 9(b). The Amended Answer (¶¶120-168) provides the "who, what, when, where, and how of the material misrepresentation or omission committed before the PTO." *Exergen Corp. v. Wal-Mart Stores, Inc.*, 575 F.3d 1312, 1327 (Fed. Cir. 2009).

All of these factors point to allowance of the Amended Answer. *See Helios Software, LLC v. Awareness Techs., Inc.*, 2013 WL 6773658, at *2 (D. Del. Dec. 19, 2013) (granting motion for leave to amend the answer to add counterclaim and defense of inequitable conduct almost a year after the deadline for amendments to pleadings); *Galderma Laboratories Inc. v. Amneal Pharmaceuticals, LLC*, 2013 WL 5461611, at *1-2 (D. Del. Sept. 30, 2013) (granting motion to amend the answer to add affirmative defense and/or counterclaims of unenforceability due to inequitable conduct, unclean hands, and breach of contract).

Roche contacted counsel for Enzo with respect to its position on Roche's motion for leave to amend and provided its proposed amended answer but has not been informed as to its consent or opposition.

II. CONCLUSION

Roche therefore respectfully requests that this Court grant it leave to file the First Amended Answer to the Amended Complaint and Counterclaims, attached hereto as Exhibit A.

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CERTIFICATE OF SERVICE

I hereby certify that on January 15, 2014, I caused to be served copies of the foregoing document in the manner indicated below and electronically filed the same with the Clerk of Court using CM/ECF which will send notification of such filing(s) to the following counsel of record:

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